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VIA ECF

The Honorable Robert Kugler
Senior United States District Court Judge
District of New Jersey

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Kugler and Judge Schneider:

On behalf of the Defendants' Executive Committee, this letter is to provide Defendants' positions with respect to the topics on the agenda for the conference with the Court on November 24, 2020.

1. Rule 30(b)(6) Notices and Objections

On October 16, 2020, Plaintiffs served Notices of Rule 30(b)(6) Deposition (the "Notices") on each Manufacturer Defendant. The Manufacturer Defendants served responses and objections to the Notices on October 30, 2020. The Parties have met and conferred on the Notices and have exchanged a number of drafts in an effort to reach agreement on the scope of the requests. Following the meet and confer process, several disputes remain.

Rule 30(b)(6) specifically requires that a notice for deposition of a corporate designee "must describe with reasonable particularity the matters for examination[.]" Fed. R. Civ. P. 30(b)(6). This particularity is necessary to "give the opposing party notice of the areas of inquiry that will be pursued so that it can identify appropriate deponents and ensure they are prepared for the deposition." *Tri-State Hosp. Supply Corp. v. United States*, 226 F.R.D. 118, 125 (D.D.C. 2005); *see also Prokosch v. Catalina Lighting, Inc.*, 193 F.R.D. 633, 638 (D. Minn. 2000) ("[T]o allow the Rule to effectively function, the requesting party must take care to designate, with painstaking specificity, the particular subject areas that are intended to be questioned, and that are relevant to the issues in dispute.").

a. Global Disputes

i. Jurisdiction

The Court's jurisdiction over the Manufacturer Defendants has not been established. Though the Court directed that Defendants' Motions to Dismiss should exclude challenging personal jurisdiction under Rule 12(b)(2), in Defendants' Memorandum of Law in Support of their Motion to Dismiss, Defendants reserved all applicable personal jurisdiction defenses and requested leave to file a memorandum addressing personal jurisdiction defenses. ECF No. 520-3 at 9 n.12. Before the Manufacturer Defendants expend the significant resources and employee time required to prepare corporate designees to testify regarding the extensive topics identified in the Notices,[1] the Court should rule on the question of whether it has jurisdiction over each noticed Defendant. To that end, Defendants reiterate their request for supplemental briefing on their personal jurisdiction defenses.

ii. Limitation to Valsartan for Sale in the United States Market

The Notices include topics seeking information regarding *all* of the Manufacturer Defendants' valsartan API and finished dose products, whether intended for the United States market or not. These topics reach far beyond the scope of the Court's Macro Discovery Order (ECF No. 303). This Court has made clear that "[t]he case involves sales of Valsartan in the United States and that is where the focus of plaintiffs' discovery should and will be," and limited the scope of discovery accordingly. 11/20/19 Oral Op. at 20:24-21:1. As part of discovery, the Rule 30(b)(6) depositions should also be limited to the product at issue in this case – valsartan API and finished dose for sale in the United States.

iii. Deposition Topics Addressing Foreign Regulatory Matters

To the extent that they seek information regarding foreign regulatory activities, correspondence, and documentation, each of the Notices should be limited to conform with the scope of discovery set out in the Court's Macro Discovery Order. ECF No. 303 at ¶ 6. Accordingly, the terms "communications with any regulatory authority," "disclosures to regulatory authorities," and "filings with regulatory authorities" are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

[1] Plaintiffs' Second Amended Notice of Videotaped Deposition to Zhejiang Huahai Pharmaceutical Co., Ltd. Pursuant to Fed. R. Civ. P. 30(b)(6) (the "ZHP Notice"), for example, requests the testimony of corporate designee(s) on fifty-nine separate topics.

iv. Relevant Time Period

As drafted, the Notices set no limitation on the time period applicable to the information requested. The applicable Defendant-specific relevant time periods set out in the Court's Macro Discovery Order should apply to the Notices. *See* ECF 303 at ¶ 10.

v. Scope of Requests Relating to cGMPs, Standard Operating Procedures, Policies, and Procedures

The Notices include several requests for the Manufacturer Defendants to provide corporate designees to testify regarding "cGMPs," "standard operating procedures" ("SOPs"), "policies" and "procedures." *See, e.g.,* Exhibit A at Request Nos. 21-24. CGMPs, SOPs, policies, and procedures all constitute extremely broad and overinclusive categories of documents, and the majority of the responsive information bears no relation to the cause or detection of the presence of NDMA and/or NDEA in valsartan. These requests are plainly overbroad and lack the reasonable particularity required under the Federal Rules. *See* Fed. R. Civ. P. 30(b)(6). This particularity is not a mere technical requirement – the Manufacturer Defendants need to understand which cGMPs, standard operating procedures, policies, and procedures may be at issue in a deposition in order to provide adequately-prepared corporate designees. To provide the particularity necessary for adequate preparation of a corporate designee, the Manufacturer Defendants propose limiting topics relating to cGMPs, SOPs, policies, and procedures to be limited to matters referenced in FDA correspondence and FDA documents relating to the investigation into the presence of NDMA and/or NDEA in valsartan manufactured by the Manufacturer Defendants.

vi. Timeframe for Providing Sample Documents

The Notices indicate testimony on yet-unidentified "sample" documents containing sales and pricing data. *See, e.g.,* Exhibit A at Request Nos. 58-59. The Manufacturing Defendants request that these sample documents be identified at least 60 days in advance of the deposition, to ensure that appropriate designee(s) can be identified and prepared to testify as to each Manufacturer Defendant's knowledge on these issues.

vii. "Actual or Potential Contamination"

The most recent drafts of the Notices also make several requests relating to "actual and potential nitrosamine contamination." *See, e.g.,* Exhibit A at Request No. 20 (E.g., "The extent of the actual and potential nitrosamine contamination of ZHPs valsartan API and finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches."); *see also id.* at 40. The term "potential contamination" is overbroad, vague, ambiguous, invites speculation, and should be stricken.

Additionally, the term "contamination" is itself objectionable. The NDMA and NDEA nitrosamines alleged in the Master Complaints are impurities. Generic drugs may contain impurities not present in their branded equivalents without the generic drugs being "contaminated." *See* FDA, *Guidance for Industry ANDAs: Impurities in Drug Products* (2010), available at https://www.fda.gov/files/drugs/published/ANDAs--Impurities-in-Drug-

Products.pdf. The Manufacturer Defendants are willing to produce corporate designee testimony on these topics insofar as they relate to the presence of actual NDMA and NDEA impurities in valsartan, and the Notices should be modified accordingly.

b. Defendant-Specific Disputes

i. Aurobindo

Counsel for the Aurobindo parties met with Plaintiffs' Counsel on October 20, 2020 regarding Plaintiffs' list of priority custodians. On November 5, 2020, the parties had a productive meet-and-confer regarding Plaintiffs' 30(b)(6) Notice directed to the Aurobindo parties. Plaintiffs then served a redline version of a Second Amended 30(b)(6) Notice to Aurobindo on November 6, 2020. In response, Aurobindo served proposed redlines to Plaintiffs' draft and the parties met and conferred further on November 16, 2020. Aurobindo received a few additional edits from Plaintiffs on November 19 and 22. On November 23, Aurobindo responded and Plaintiffs sent a Third Amended 30(b)(6) Notice. The remaining issues are the global issues concerning jurisdiction, timeframe, topics regarding SOPs and cGMPs, and use of the term "potential" throughout the Notice, for the reasons discussed above. Attached as Exhibit B, please find a redline version of Plaintiffs' Third Amended 30(b)(6) Notice to Aurobindo.

i. Hetero Labs

Counsel for Hetero Drugs and Hetero Labs ("HLL") have met and conferred with Plaintiffs on November 4, 2020 and November 13, 2020, and have exchanged a number of drafts in an effort to reach a resolution on the topics to be covered in HLL's 30(b)(6) Deposition. Other than the global issues set forth above by Defendants, Plaintiffs and HLL are continuing to meet and confer with respect to a limited number of topics for which HLL may not have sufficient knowledge to testify on. HLL anticipates reaching an agreement with Plaintiffs on these remaining issues shortly.

ii. Mylan

Since they served their initial objections on October 30, the Mylan Defendants have made clear that—subject to the jurisdictional issues highlighted above—they are prepared to produce a witness or witnesses reasonably prepared to offer testimony regarding the core issues in this case, including: (i) the root cause analysis with respect to trace levels of NDEA detected in some batches of valsartan API; (ii) chromatography testing with respect to genotoxic impurities and residual solvents performed on valsartan API and valsartan-containing finished-dose product; (iii) the medical risk assessment performed in connection with the voluntary recall of valsartan-containing medications in the United States; (iv) the steps involved in the valsartan API manufacturing process which have been identified through Mylan's root cause analysis as the source of potential trace levels of NDEA impurity; and (v) the dates of Mylan's voluntary recalls of valsartan-containing medications from the United States market were announced, the content of those notices of voluntary recall, the recipients of those notices of voluntary recall, the means by which

those notices of voluntary recall were disseminated, and Mylan's handling of recalled and returned valsartan finished-dose product.

Nonetheless, the Mylan Defendants maintained that many of the topics identified by Plaintiffs in the original and first amended notices were overly broad, redundant, disproportionate, and irrelevant. Indeed, in addition to the "global" disputes identified above and in terms of "big picture" items, the Mylan Defendants objected on the basis that Plaintiffs were improperly demanding corporate testimony regarding third parties and unidentified "agents" and entities ostensibly "known to" Mylan to have played some role in the manufacture of valsartan drug substance and drug product. Those requests do not provide sufficient specificity for the Mylan Defendants to identify and prepare a witness and, regardless, represent an improper expansion on the Rule 30(b)(6) mechanism. Second, the Mylan Defendants objected to the extent Plaintiffs demanded testimony regarding testing other than chromatography testing with respect to genotoxic impurities and residual solvents, because it is beyond the scope of relevant discovery in this litigation. Third, as spreadsheets detailing—by lot/batch number, date, customer, amount, and product—all valsartan API and finished-dose product sold in the United States from market entry through global recall have already been produced, the Mylan Defendants maintained that further testimony regarding so-called "product tracing" was unnecessary.

On Saturday, November 21—just three days before the scope of corporate representative depositions is to be argued before the Court—Plaintiffs served a second amended Rule 30(b)(6) notice of deposition directed to the Mylan Defendants. Exhibit C. Whereas it was expected Plaintiffs would narrow their requests in response to the Mylan Defendants' objections served nearly a month ago, the second amended notice purports to significantly expand the scope of the testimony Plaintiffs would demand from the Mylan Defendants. Indeed, the second amended notice lists 54 matters for examination—an increase of 12 (or nearly 30%) from Plaintiffs' original notice. Moreover, whereas Plaintiffs' original and first amended notices were expressly limited to valsartan API and finished-dose product sold in the United States, Plaintiffs now demand testimony regarding all valsartan API and finished-dose products manufactured by Mylan "regardless of intended sale location."

As previously stated, the Mylan Defendants have received approval to manufacture valsartan-containing medications ("VCMs") from no fewer than 14 countries/regulatory bodies—United States, Australia, Albania, Bosnia and Herzegovina, Costa Rica, Ecuador, Jamaica, Japan, Myanmar, Panama, El Salvador, Tanzania, Zimbabwe, and the European Medicines Agency (which would include all 28 member states, plus Iceland, Norway, and Lichtenstein)—and, in the last several years, have sold VCMs in approximately 46 countries. But not a single plaintiff in this MDL resides outside of the United States. Accordingly, the Court has already made clear when deciding macro discovery issues, discovery in this litigation is to be focused on valsartan-containing medication sold in the United States.

Thus, it is the Mylan Defendants' position that the second amended notice is procedurally improper insofar as it represents an attempt to materially expand the number and scope of topics to be addressed by Mylan's corporate representatives well beyond the deadline for Plaintiffs to

disclose their proposed topics, thereby leaving Mylan insufficient time to formulate objections and preventing the parties from engaging in a fulsome meet and confer. Plaintiffs' second amended notice is also substantively overbroad because, inter alia, it purports to require testimony beyond the limits established by the Court's "macro" discovery rulings entered last year. Finally, upon initial review, it does not appear that the scope of the testimony demanded from the Mylan Defendants has been narrowed in any meaningful way through the second amended notice and, therefore, the Mylan Defendants incorporate by reference their objections served on October 30.

iii. Teva

Teva and Plaintiffs first met and conferred regarding corporate witnesses on October 15, 2020, with general discussion regarding the witnesses, their roles, their locations, and languages. Teva and Plaintiffs then met and conferred again more specifically on the 30(b)6 topics on Tuesday, November 17, 2020, after which Plaintiffs sent a Second Amended 30(b)(6) Deposition Notice to Teva on Thursday, November 19, 2020, which incorporated only modest revisions. The parties held another lengthy meet and confer on Saturday, November 21, 2020, after which Plaintiffs' counsel sent a Third Amended Notice to Teva. Teva responded on Sunday, November 22, 2020, with a redline draft indicating the language required to resolve Teva's pending objections without further argument before the Court. The parties exchanged additional redlines again on Monday, November 23, 2020. Attached for the Court's consideration as Exhibit D and E, respectively, are Plaintiffs' Third Amended Notice to Teva, along with Defendants' redline response showing edits required to resolve Teva's pending objections.

Teva Based on language provided by Plaintiffs on November 23, 2020, Teva believes that issues regarding foreign regulatory agencies have been resolved. However, in addition to the global issues outlined above, several issues remain as to Teva, consistent with those described by Mylan above:

- Specific language regarding the scope of relevant testing with respect to Teva's finished dose products.
- Whether Teva will be asked to provide a witness to testify as to information known to third-parties who are neither Teva affiliated entities nor agents of Teva.
- Specific language regarding the scope of relevant products as being limited to Teva's finished dose product manufactured for sale in the United States.

The Teva Defendants will be prepared to address these issues at the November 24, 2020 Case Management Conference.

iv. Torrent

Torrent has engaged in multiple meet and confers with Plaintiffs regarding Plaintiffs' Rule 30(b)(6) notice and believes the parties have made significant progress toward narrowing Plaintiffs' overbroad notice. Plaintiffs sent Torrent a third amended Rule 30(b)(6) notice on November 23, 2020, which Torrent is evaluating.

v. ZHP

The most recent draft of the ZHP Notice defines the scope of ZHP's obligations to provide information as follows: "All topics reference information and documents known to, and/or in the possession, custody, or control of ZHP, in the ordinary course of its business." *See* Exhibit F at 4.

Plaintiffs further assert that ZHP is obligated to prepare its witnesses to testify regarding information "accessible" through the separate defendants Solco Healthcare US, LLC ("Solco"), Huahai US Inc. ("Huahai"), and Prinston Pharmaceutical Inc. ("Prinston"), each of which is a corporate entity distinct from ZHP. This "accessible" standard is ambiguous and differs from the standard set out by the Federal Rules of Civil Procedure. *See* Fed. R. Civ. P. 34(a)(1) (limiting a party's discovery obligations to information within that party's "possession, custody, or control."). In accord with the Federal Rules of Civil Procedure, ZHP's obligation to produce corporate designees knowledgeable about the ZHP Notice's topics should extend only to information within ZHP's possession, custody, or control in the ordinary course of business.

Moreover, the ZHP Parties have agreed, subject to the pending objections, to produce a corporate designee from produce testimony on *each* of the topics listed in the ZHP Notice. Defendants Solco, Huahai US, and Prinston have agreed to produce witnesses on the Rule 30(b)(6) deposition topics to the extent they pertain to information primarily within their own possession, custody, or control in the ordinary course of business, and Plaintiffs have served separate Notices on each of these Defendants.

2. Deposition Protocol Addendums

a. Chinese Entity Addendum

The main objective of the Supplemental Protocols Governing Depositions of Chinese Nationals Residing in Mainland China (the "Chinese Addendum") is to provide certain safeguards for Chinese witnesses who agree voluntarily to be deposed in this action, which, to avoid criminal prosecution under China law, will require them to travel at least ten hours to a different country to be deposed. Given the unquestionable health risks posed to the witnesses and their families by such travel during the ongoing global pandemic, and the gauntlet of travel restrictions, mandatory quarantines, and community shut-downs being imposed worldwide due to COVID-19, such safeguards are not only reasonable, they are essential. The health and safety of Chinese citizens should not be jeopardized by their voluntary participation in a U.S. civil litigation, especially considering that the timing of their depositions presents no risk of harm to any Plaintiff because any allegedly impure valsartan was recalled more than two-years ago.

Despite the Court's repeated observations that the depositions of Chinese nationals during the global pandemic presents "***very, very sticky issues***," (Tr. of 9-16-20 Hrg. at 14:2; *id.* at 21 (THE COURT: "[I]t's an ***amazingly complex*** situation that's complicated by the fact that we have foreign defendants and we're in the midst of this pandemic. So it's a ***perfect storm***." (emphasis added)); Tr. of 9-30-20 Hrg. at 25; Tr. of 10-14-20 Hrg. at 24-25), Plaintiffs refuse to agree to terms in the Chinese Addendum acknowledging, among other things: (1) the depositions are

voluntary; (2) the potential for criminal prosecution under China state secret and privacy laws; and (3) the burden to witness of traveling 10-hours, by means of public transportation, to Hong Kong with the concomitant risk of exposure to COVID-19 for the witness and their families. Instead, Plaintiffs insist on terms that actually frustrate the completion of these depositions—contrary to this Court's observations and decisions by other courts around the country mandating flexibility in scheduling foreign depositions during the pandemic. *See, e.g.*, *Willis Elec. Co. v. Polygroup Macau Ltd.*, No. 15-cv-3443, 2020 WL 3397359, at *2 (D. Minn. June 19, 2020) (affirming Magistrate Judge's order requiring the parties "to be flexible and understanding about how and when to schedule these depositions [in Hong Kong] as the reality of the [COVID-19] virus and its impact on international travel continue to evolve"); *see supra* at Section 2.a.iii.

Significantly, there are only a handful of Chinese nationals that should be deposed in this action. While Plaintiffs have identified 15 ZHP employees as potential fact witnesses, ZHP expects that five to six of those employees can be designated to cover all of the topics in the 30(b)(6) notice Plaintiffs served on ZHP, eliminating the need for the depositions of the other proposed fact witnesses. Plaintiffs have said numerous times that they intend to use the 30(b)(6) notice to streamline the number of depositions.[2] Thus, were the Court to agree that Chinese witnesses should not be expected to travel to Hong Kong until the COVID-19 restrictions are lifted, and were Plaintiffs to make good on their promise regarding streamlining the number of depositions, any delay of the depositions of the 5-6 ZHP employees due to COVID-19 would not delay these proceedings. Plaintiffs can proceed under the current schedule with fact depositions of US employees of ZHP, and depositions of witnesses for the other Defendants have also been ordered.

For these reasons, and those described below, ZHP respectfully requests the Court approve the following terms of the Chinese Addendum, as drafted by Defendants. For the Court's convenience, a chart setting for the parties' respective proposals as to these terms and others in the Chinese Addendum is attached as Exhibit G:

i. The Voluntary Nature of the Depositions (*see* Chinese Addendum §§ A.1, B.6)

Sections A.1 and B.6 of the Chinese Addendum acknowledge that Chinese nationals residing in China may only be deposed in this litigation upon their voluntary agreement, as they are "beyond the subpoena power of [U.S.] courts[.]"[3] And no depositions can take place in China

[2] *See, e.g.*, Tr. of 10-28-20 Hrg. at 11 (MR. SLATER: "[W]e started to discuss those prioritized people for depositions at least as a starting point plus trying to get identification of who would be the designated corporate representatives, and, you know, it's our hope, . . . that we can work together to try to be practical in terms of, for example, who gets designated as a corporate representative, so that . . . as we've discussed previously, [we can] try to maybe reduce the number of fact depositions we ultimately have to take as best we can.").

[3] *In re Petition of Boehringer Ingelheim Pharm., Inc., & Boehringer Ingelheim Int'l GmbH, in Pradaxa (Dabigatran Etexilate) Prod. Liab. Litig.*, 745 F.3d 216, 218 (7th Cir. 2014).

– whether in-person or remote or voluntary or compelled – without first obtaining permission from the Chinese government through the Hague Evidence Convention (the "Hague").[4] Due to the voluntary nature of these depositions, which requires the witness travel to another country, the safeguards ZHP has proposed in the Chinese Addendum are necessary, and Sections A.1 and B.6 regarding the voluntary nature of the depositions should be approved.[5]

ii. References to International Laws and Requisite Chinese Attorney Attendance (*see* Chinese Addendum §§ A.3, A.4, C.16, C.17)

Plaintiffs have provided no basis to strike Sections A.3, A.4, C.16, and C.17, which incorporate the Hague, China's Civil Procedure Law ("CPL"), and China's state secret laws into the Chinese Addendum.

While all of the legal references serve a distinct purpose,[6] the recognition of Chinese state secret laws is essential because China imposes criminal and civil penalties on any individual who transmits China's "state secrets" outside of China. *See* People's Republic of China State Secrecy Law, at Art. 31 and Criminal Law of the People's Republic of China, at Art. 111 ("Whoever . . . supplies State secrets or intelligence [to] an individual outside the territory of China shall be sentenced to fixed-term imprisonment of not less than five years but not more than 10 years; if the circumstances are especially serious, he shall be sentenced to fixed-term imprisonment of not less than 10 years ***or life imprisonment***[.]" (emphasis added)).

ZHP believes there are four categories of "state secret" information that may be implicated during the depositions:

> Information that the Chinese government has expressly required ZHP to keep confidential;
>
> Confidential internal documents of Chinese government authorities;

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[4] U.S. Dep't of State, Bureau of Consular Affairs, *China Judicial Assistance Information*, *Taking Depositions of Voluntary Witnesses*, available at https://travel.state.gov/content/travel/en/legal/Judicial-Assistance-Country-Information/China.html ("China has indicated that taking depositions, whether voluntary or compelled, and obtaining other evidence in China for use in foreign courts may, as a general matter, only be accomplished through requests to its Central Authority under the Hague Evidence Convention.").

[5] Section A.5 of the Chinese Addendum preserves any jurisdictional defenses ZHP or Chinese witnesses may have. As discussed herein, *see* Section 1.a.i, the Court has not permitted Defendants to brief those defenses, but has acknowledged they are preserved.

[6] The reference to the Hague should be approved because it provides flexibility should the parties agree to another location where the Hague is applicable. China's CPL, together with the Hague, provide the restrictions on conducting depositions in China for use in foreign litigations, and thus result in the voluntary nature of these depositions.

> Documents and communications recording the contents of confidential meetings and communications with Chinese government authorities; and

Information regarding non-public tax policies or subsidies of the PRC government. *See* People's Republic of China State Secrecy Law, at Art. 2 and Art. 9. The risk of disclosure to ZHP, its employees, and its China-based attorneys is disproportional to any benefit that Plaintiffs could hope to obtain among these four very narrow categories of information.

The Chinese Addendum also provides for the attendance at the deposition of an attorney with expertise in China trade secret and privacy laws, likely also a China resident, who can protect the witness. Although ZHP's witnesses will make every effort to answer the questions posed, in the event a question requires the disclosure of protected information, the witness should not be required to violate Chinese law. This approach is consistent with U.S. law, which provides that in pretrial proceedings U.S. courts should exercise vigilance to demonstrate due respect for interests expressed (through statute and otherwise) by a foreign state. *Societe Nationale Industrielle Aerospatiale v. U.S. Dist. Court*, 482 U.S. 522, 546 (1987); *see also Tiffany (NJ) LLC v. Qi Andrew*, 276 F.R.D. 143, 160 (S.D.N.Y. 2011) (quashing subpoena although the information at issue was "vital" to the plaintiff's claims because disclosure would expose the defendant to possible criminal penalties under Chinese law). Accordingly, reference to these laws and Sections C.16 and C.17 should be approved.

iii. COVID-19 Travel Restrictions and Requisite Travel (*see* Chinese Addendum §§ C.13, C.15)

Courts around the country have recognized that litigants' concerns surrounding travel during this global pandemic are entirely justified. *See, e.g.*, *Sonrai Sys., LLC v. Romano,* 2020 WL 3960441, at *2 (N.D. Ill., July 13, 2020) (noting "the general concern over the risks posed by COVID-19 are heightened" where a deposition would involve travel, participants have immediate family members in COVID-19 high-risk categories, and mandatory 14-day quarantines exist); *Zhizheng Wang v. Hull*, 2020 WL 4734930, at *2 (W.D. Wash. June 22, 2020) ("With regards to the current health crisis caused by the novel coronavirus, . . . the Court will not require, that plaintiff board a flight for Seattle, Hong Kong, Macau, Seoul, or Taipei immediately."); *In re RFC and ResCap Liquidating Tr. Action,* 444 F. Supp. 3d 967, 971-72 (D. Minn., Mar. 13, 2020) (noting the court was "very sympathetic . . . to concerns [over traveling to provide testimony], particularly in light of the many unknowns inherent in a virus outbreak"). Through absolutely no fault of the handful of potential witnesses located in China, travel is unavoidable here.

Courts have dealt with this unique challenge by delaying depositions until the COVID-19 pandemic has subsided or, at least, until travel and mandatory quarantines are not so burdensome. *See, e.g.*, *Jacobs v. Floorco Enterprises, LLC*, No. 3:17-cv-90, 2020 WL 1290607, at *16 (W.D. Ky. Mar. 18, 2020) (ordering that a Chinese resident must travel for his deposition but "not yet impos[ing] a deadline as to when" in light of personal circumstances and "the current restrictions imposed by the United States and other countries on travel in light of COVID-19"); *Mun v. R.J.*

Annabelle, Inc., No. 2:19-cv-2470, 2020 WL 4904654, at *2 (C.D. Cal. Apr. 15, 2020) (ordering the deposition of a witness in China to occur "one month after the end of the COVID-19 emergency in California, assuming travel from China is permitted by that time")); *Willis Elec. Co.*, 2020 WL 3397359, at *2; *c.f.* Practical Law Litigation, *Expert Q&A on Remote Depositions*, at 4, available at https://www.cravath.com/a/web/12861/5455513-1.pdf ("Alternative means of dealing with restrictions, such as having the witness travel to a nearby jurisdiction with more permissive deposition rules (for example, Finland instead of Russia, or Hong Kong instead of mainland China), may not be feasible while COVID-19 travel restrictions are in place.").

Consistent with the above decisions, Section C.15 ensures the depositions of Chinese nationals will not occur until the COVID-19 restrictions and travel quarantines are lifted. A Chinese national should not be expected to travel 10 hours to Hong Kong via public transportation under the current restrictions, which require quarantine in isolation for at least 28 days—14 days upon arrival in Hong Kong and 14 days upon return to China. Moreover, as with most countries, the current surge of COVID-19 cases is causing intra-China restrictions that would also impede the witness's travel to Hong Kong. It cannot be reasonably disputed that the health and welfare of the Chinese witnesses and their families should not be jeopardized due to their voluntary participation in this civil litigation, especially considering that a delay of the depositions of a small handful of Chinese nationals due to COVID-19 will not impact the progress of these proceedings nor expose any Plaintiff to any harm.[7] Thus, the Court should approve Section C.15. Defendants also ask that Plaintiffs be required to demonstrate good cause in order to require witnesses to travel to Hong Kong (and potentially expose themselves to COVID-19) more than one time. *See* Section C.13.

iv. Location and Length (*see* Chinese Addendum §§ C.8, C.10)

Plaintiffs have not proposed an alternative location to Hong Kong at all—let alone one that takes into account the legal landscape, burden on the witnesses, visa or travel permit permissiveness, and international COVID-19 restrictions. Instead, Plaintiffs focus on the difficulties they would personally face because of the time-zone disparity with Hong Kong. *See* Chinese Addendum §§ C.10, C.12. Plaintiffs' proposed language provides no certainty as to how many days a witness will be stuck in Hong Kong. Accordingly, the Court should approve Defendants' compromise that a deposition will occur over two consecutive days, beginning at 7:00 a.m. Hong Kong Standard Time (7:00 p.m. Eastern) and ending at 12:00 p.m. Hong Kong Standard Time (12:00 a.m. Eastern).

[7] It is worth noting that Plaintiffs' counsel has indicated a complete unwillingness to travel to Hong Kong, or anywhere else for that matter, for the depositions in this case due to concerns for their own health and safety given COVID-19. It is obviously unfair for Plaintiffs to insist nonetheless that witnesses should risk their health and safety.

v. Translation of Exhibits (*see* Chinese Addendum § C.20)

To maximize the use of deposition time, Defendants propose Section C.20, which provides a procedure for the parties to agree in advance of the depositions on the translated versions of documents that may be used. The exhibits for depositions subject to this addendum must be translated in both Chinese and English and will contain many technical and scientific terms. Translating these documents in advance will allow the parties to verify the accuracy of the proposed translations, therefore optimizing the efficient use of deposition time. Yet, Plaintiffs' proposed language makes this procedure optional, which defeats Section C.20's entire purpose.[8]

vi. Disparagement and Observance of Chinese Holidays (*see* Chinese Addendum §§ C.18, C.19)

It is undeniable that Chinese government, heritage, and culture differ in a number of respects from American government, heritage, and culture. However, there should never be any reason for counsel to comment negatively on such differences. Regrettably, such comments have already been made during these proceedings. Disparaging comments about Chinese government, heritage, and culture at a deposition would cause disruption and impede a witness's testimony and thus should be explicitly prohibited as set forth in Section C.19.

Similarly, ZHP has proposed language respecting the observance of the Chinese New Year, *see* Section C.18, which is an important government-mandated holiday in China, during which most Chinese nationals are expected to travel throughout the country for an extended period. *See D.Light Design, Inc. v. Boxin Solar Co.*, 2014 WL 12659908, at *1 n.2 (N.D. Cal. Jan. 29, 2014) (acknowledging the Chinese New Year is a holiday "of particular importance to persons living in China" and that "many of the businesses or persons involved will not be operating or available because of the holiday").

b. Indian Entity Addendum

The parties have engaged in a meet and confer regarding the Indian Entity Addendum to the deposition protocol, and have resolved some of the issues in dispute. The Defendants' proposed version of the India Entity Addendum is attached as Exhibit H. Three macro areas of dispute remain.

[8] In the event the Court disagrees with Defendants' language in Section C.20, Defendants ask that time spent at the deposition for a deponent and the deponent's translator to review the documents and disputes regarding the accuracy of translations be counted against Plaintiffs' time-limit. The Court has already ruled that the time of depositions requiring the use of translators is increased by 75%. *See* Case Management Order No. 20.

i. Hague Evidence Convention

Plaintiffs refuse to agree to the inclusion of language that would preserve the right of Indian nationals who are called to testify in their individual capacities to require notice in accordance with the Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters. Rather, Plaintiffs ask this Court to disregard the Hague Evidence Convention out of hand, and to require that any deposition of an Indian national must be conducted solely in accord with the Federal Rules of Civil Procedure. This is inconsistent with Third Circuit jurisprudence, which states that the applicability of the Hague Evidence Convention should be considered on a case-by-case basis. Specifically, the Third Circuit has adopted the Supreme Court's a three-pronged balancing test that weighs (i) the particular facts at issue, (ii) the sovereign interests in the resolution of the litigation, and (iii) the likelihood of success in conducting discovery under the Hague protocols to determine whether the Federal Rules or the Hague Evidence Convention should control. *In re Auto. Refinishing Paint Antitrust Litig.*, 358 F.3d 288, 300 (3d Cir. 2004) (citing *Societe Nationale Industrielle Aerospatiale v. U.S. Dist. Ct. for S. Dist. of Iowa*, 482 U.S. 522, 534 (1987)).

India is a signatory to the Hague Evidence Convention. *See, e.g.*, *Life Bliss Found. v. Sun TV Network Ltd.*, EDCV 13-00393-VAP, 2014 WL 12598859 (C.D. Cal. May 8, 2014) (requiring Plaintiffs to Comply with Hague Evidence Convention by obtaining prior permission from the Indian Central Authority for the Hague Evidence Convention before conducting deposition of Indian national). Accordingly, Defendants seek to preserve the ability of foreign national witnesses to require notice under the Hague Evidence Convention before sitting for deposition.[9] The Indian Manufacturers believe such a reservation is necessary in light of unresolved issues in this litigation. Specifically, questions regarding whether there is personal jurisdiction over the Indian Manufacturer Defendants have not yet been briefed, much less decided. Further, Plaintiffs have identified a number of Indian National employees as potential fact witnesses, but have been non-committal with regard to the number of depositions Plaintiffs will ultimately seek. Finally, to the extent Plaintiffs argue that it will cause undue delay to secure Indian national depositions under the Hague protocols, this is mere speculation. To date, Plaintiffs have not made any attempt to comply with the Hague protocols.

Through further negotiation with regard to potential deponents, it is possible that the parties can reach agreement that would obviate the need to proceed under the Hague Evidence Convention. In the interim, all that Defendants ask is that the issue be preserved in the Deposition Protocol.

[9] This reservation would apply only to individual fact witnesses. Indian nationals who are designated to testify as 30(b)(6) witnesses will be produced in accordance with the Federal Rules of Evidence.

ii. Timing of Depositions

Plaintiffs have proposed language that would allow depositions to of Indian nationals to be conducted in "blocks" over a number of days as opposed to during one, consecutive seven-hour session. The Indian Manufacturer Defendants do not agree, and maintain that depositions should be conducted during business hours based on the location of the witness. Depositions of corporate representative witnesses in their individual capacity should also occur on consecutive days with Rule 30(b)(6) dispositions whenever possible.

iii. Reservation of Right to object

Defendants seek to reserve the right to raise objections to individual deposition notices. Contrary to Plaintiffs' assertions, such objections are not ripe this time as notices of depositions have not yet been served, and no depositions have been taken.

c. Israeli/EU Addendum

Teva's witnesses are primarily in the United States, and we do not expect the foreign deposition process to present any significant barriers, however a number of Teva's potential witnesses do reside in either Europe or Israel. During the meet and confer process over Teva's witnesses, Teva discussed the potential need for an Addendum and further attempted to determine which of Teva's witnesses Plaintiffs will insist upon deposing in their individual capacity so that Teva could assess the potential need for its own Addendum to address the taking of individual depositions in Europe and Israel. Plaintiffs could not provide an answer to this question. Accordingly, Teva determined that such an Addendum may be necessary, and on Sunday November 22nd, Teva forwarded a draft proposal for discussion, which largely tracks the Indian Addendum Plaintiff has been negotiating. *See* Exhibit I.

With respect to the depositions of non-US nationals residing in Israel or European Union ("EU") countries, the Plaintiffs' ability to conduct depositions of these individuals may require compliance with the Hague Evidence Convention. Plaintiffs may depose non-US nationals residing in Israel or the EU pursuant to the Federal Rules of Civil Procedure insofar as a witness is designated as a corporate representative of a properly served Defendant entity pursuant to Rule 30(b)(6). In order to obtain deposition testimony from witnesses testifying in their individual capacities, however, Plaintiffs need to avail themselves of the Hague Evidence Convention, unless the individual witness otherwise agrees to waive proper service under the Hauge, which requires obtaining a commission from the relevant Central Authority for the country where the witness is located under the The Hague Evidence Convention. "[T]he determination of whether to resort to the [Hague] Convention requires 'prior scrutiny in each case of the particular facts, sovereign interests, and likelihood that such resort will prove effective.'" *In re: Auto. Refinishing Paint Antitrust Litig.*, 358 F.3d 288, 300 (3d Cir. 2004) (quoting *Societe Nationale Industrielle Aerospatiale v. United States Dist. Court for the S. Dist. of Iowa*, 482 U.S. 522, 544 (1987) (establishing the three-prong test for determining whether to utilize the FRCP in securing a foreign witness deposition or to utilize the Hague Convention).

The Teva Defendants commit to working with Plaintiffs to avoid the need to employ Hague service in securing the depositions of Teva's witnesses where possible. However, circumstances may arise—for example, if a witness no longer employed by Teva—which might necessitate that the parties resort to the Hague procedures. *See AstraZeneca v. Ranbaxy Pharm., Inc.*, Civil Action No. 05-5553 (JAP), 2008 U.S. Dist. LEXIS 6337 (D.N.J. Jan. 25, 2008). (granting Defendants' motion to for a letter requesting international assistance in securing the depositions of Plaintiffs' foreign witnesses under the Hague Convention).

In addition, the Defendants' proposed Addendum Governing Depositions of Israeli and European Union Nationals Residing Outside the United States contains similar provisions related to COVID-19 restrictions, translators, and the location, number and length of depositions as those in the Indian Addendum.

3. Defendants' Proposed CMO on General Causation and Class Certification Briefing and Discovery

The Court has heard Defendants' requests to pursue general causation discovery and work-up of the personal injury cases on several prior occasions, and Judge Kugler has specifically acknowledged that "we need to start a parallel track on what defense calls general causation or might be called the bodily injury and personal injury case." 9/30/20 CMC Transcript at 49:7-10. At the same time, the Court made clear that "there needs to be sometime mid next year, service of expert reports on [general causation] issues and Daubert hearings, if necessary. *Id.* 49:16-18. The Court has been clear on its intention that this discovery proceeding in parallel, not bifurcated or delayed fashion. The Court has stated its intention to enter a scheduling order memorializing this plan at the November CMC. To that end, On October 30, 2020 Defendants submitted a revised proposed Case Management Schedule to Plaintiffs setting forth reasonable proposed deadlines for general causation discovery and Daubert briefing, as well as for class certification briefing. *See* Exhibit J. On November 16, 2020 Plaintiffs provided Defendants with their proposed draft, which was a complete rewrite of the schedule and takes a fundamentally different approach from that discussed by the Court at the September CMC. See Exhibit K. In fact, Plaintiffs' proposed schedule wholly ignores the Court's pronouncement regarding parallel tracks and instead seemingly bifurcates this MDL into two separate tracks: one for consumer and third-party payor class actions, followed approximately six months later by the personal injury and medical monitoring class actions. This fundamental difference lies at the core of the parties' inability to make progress on a reasonable schedule.

General causation is a necessary element, without which Plaintiffs cannot carry their burden of proof as to <u>any</u> claim. While Plaintiffs acknowledge that even the consumer class actions will require proof of general causation, they somehow believe it follows a different standard or incorporates different evidence than as will be required in the personal injury actions. To the contrary, general causation – namely whether the presence of the impurities at issue can and does cause cancer thereby rendering the drug "dangerous" as alleged in each of the Master Complaints – is the same regardless of the theory pled. Whereas the presentation of such evidence may differ depending on the type of trial, the proof required and the issues addressed should be largely the

same. Yet Plaintiffs want to have two "bites at the apple" on general causation and have therefore written in duplicative deadlines, six months apart, for general causation discovery to be addressed twice in this litigation. Such a schedule is unfair and inefficient, where the issue is straightforward and common to all claims. Accordingly, there should be one set of deadlines for general causation, starting with expert disclosures, through depositions, and Daubert briefing, and such rulings should stand as the law of the case for all claims.

Additionally, efficiency demands that the general causation be addressed prior to class certification, given that it is a threshold issue that applies across the board in all cases. To the extent Plaintiffs cannot meet their burden on general causation, the class actions necessarily fail. As this Court has pointed out, there have been no motions or order to bifurcate merits discovery from the class certification issues. Accordingly, general causation discovery and briefing should proceed before the class discovery and briefing.

In addition to this fundamental difference in approach, the Parties identified the following additional disputes as between the competing drafts, and Defendants will be prepared to discuss each point in turn:

a. Changes to Introductory/General Language:

1. Plaintiffs added: "This Order provides for interim scheduling deadlines applicable to certain parties and claims, and it is anticipated that further Orders will be entered addressing other parties and claims as the litigation proceeds." Plaintiffs' position is that this CMO does not apply to retailers and wholesalers, however the provision is not clear as to which parties and claims it does apply.

2. Plaintiffs deleted the trial case selection paragraph, which had provided for a 20/20 selection to constitute the "pool" from which personal injury trial cases would be later selected. Specifically, Defendants' language permitted Defendants to identify 20 personal injury Plaintiffs to be worked up alongside the 20 cases Plaintiffs selected for Defendant Fact Sheets for possible use as trial cases. Plaintiffs offer no alternative for selecting trial cases or otherwise determining where to start on the personal injury Plaintiff work-up. Plaintiffs stated that the DFS 20 were not intended as their best cases or a bellwether pool. From Defendants' perspective, regardless of when the personal injury depositions start, the parties need a plan for where to focus their efforts, and it is fundamentally unfair to Defendants to place all the focus on just 20 cases selected by Plaintiffs.

3. Plaintiffs deleted language that class representatives and personal injury plaintiffs' depositions could proceed on parallel tracks starting mid-January. The Court has already ordered that class representative depositions (and corporate representatives) start mid-January, and a parallel track should mean that personal injury Plaintiffs may also be deposed starting at that time. This dispute is at the core of Plaintiffs' rejection of our parallel track proposal for personal injury and medical monitoring Plaintiffs' depositions.

4. Plaintiffs deleted language reserving the Parties' rights to file Rule 56 Motions for Summary Judgment and acknowledgement that a separate order will set the schedule.

b. Specific Changes to Deadlines/Scheduling:

1. Defendants had organized the schedule into columns to distinguish deadlines for General Causation versus Class Issues. Plaintiffs changed the format to have four columns related to each type of case: consumer, third-party payer, medical monitoring, personal injury – essentially setting out four separate tracks for the same types of deadlines. Plaintiffs seek to delay the medical monitoring and personal injury track by approximately six months. Plaintiffs seek to have separate expert deadlines and Daubert deadlines for each of the four types of cases, rather than deadlines that apply to all cases. Defendants do not agree with this approach. This is reflective of the parties' fundamental disagreement.

2. Plaintiffs agree consumer class and third-party payer cases will have a general causation element and will have causation experts to be deposed, but believe it is different or less so from the personal injury cases. Plaintiffs want to treat those general causation deadlines as separate from the ones in personal injury cases. Defendants disagree and believe there is significant overlap in the general causation issues across all cases such that we should be dealing with all major issues of general causation up front for the reasons stated above. This is part of the parties' fundamental disagreement.

3. Plaintiffs have rejected a "stepped" approach to expert disclosures. Specifically, Plaintiffs removed all deadlines which required Plaintiffs to disclose (1) the types of cancer for which they will provide expert reports and (2) the disciplines and specializations of experts who will be provided to support general causation, followed by full expert reports. Defendants believe, given the complexity and number of parties and experts likely to be involved, the stepped approach would assist the orderly progression of expert discovery and help ensure the process stays on track.

4. Plaintiffs added Trial and Pretrial Deadlines, specifically setting a consumer class trial date in November 2021 and to exchange pretrial submissions in October 2021. Defendant's schedule did not set forth a specific trial date, because we believe trial setting is premature at this juncture and we should be focused on getting through general causation and class certification instead, as this Court has specifically acknowledged.

5. Plaintiffs omitted deadlines for medical monitoring class certification motions and oppositions altogether. Plaintiffs suggest the Court set those deadlines at a later undetermined time, without explanation. Defendants disagree and believe this is the appropriate place and time to include those deadlines, along with the other class certification deadlines.

6. Defendants had proposed staggering of general causation expert depositions and class certification experts, first Plaintiffs' experts, followed by Defendants' experts. Plaintiffs have combined to have one deadline for both Plaintiff/Defendants class certification expert depositions and one deadline for Plaintiff/Defendant causation experts. Plaintiffs are willing agree that

Plaintiffs' expert will be deposed first in each discipline (i.e., plaintiff epidemiologist before defense epidemiologists). Defendants feel it is necessary to depose all of Plaintiffs' causation or class certification experts before starting the depositions of Defendants' causation or class certification experts, because there will certainly be overlap among the disciplines/specialties and multiple types of experts may testify about a common issue.

7. Plaintiffs' proposal does not include deadlines for Daubert replies, and includes only opening motions and oppositions, followed by hearings. Defendants see no reason to omit reply briefing, given the critical importance of these issues.

8. Plaintiffs' proposal generally provides for different length of response and reply periods for Daubert and class certification motions than does Defendants' proposal. We are not able to reconcile the specific periods at this time until we resolve the fundamental differences mentioned above.

9. Plaintiffs added a deadline for rebuttal class certification expert reports. Defendants schedule did not have a provision for any rebuttal experts and do not believe those are necessary. This is not a case where there should be any surprise theories to rebut.

4. Plaintiff Fact Sheet Deficiency Show Cause Order Requests

a. Cases Addressed at the September 30, 2020 Case Management Conference

As a preliminary matter, Defendants note that the Court issued six (6) show cause orders returnable at the November 24, 2020 Case Management Conference. The parties have reached an agreement to extend the time to resolve the issues in two of those matters and the order to show cause is withdrawn:

- Huey, James – 19-cv-15637
- Stewart, Donald – 19-cv-21475

Four (4) cases remain subject to an order to show cause at the November 24, 2020 Case Management Conference for failure to substantially complete a PFS:

No.	Plaintiff	Civil Action No.	Law Firm	Deficiencies
1.	Battle, Dorothy	1:20-02218	Watts Guerra	*See Deficiency Notice*
2.	Fisher, Louis	20-cv-5057	Beasley Allen	Numerous deficiencies, including the following core deficiencies:

				II.D.4.c Failed to provide complete information for identified exposure III.C. Failed to respond to section re non-cancer injuries. III.C.3 Procedures and Treatments for claimed injury- Failed to respond. III.C.3.b and c List hospitalizations, procedures- Failed to respond. III.G. Failed to provide complete information re medical expenses. III.H. Failed to respond re claim for specialized damages. IV.C. and D Failed to provide complete information regarding identified pharmacies. V.E. 1 and 2. Failed to provide complete information regarding alcohol use history. IX. Fraud Claims section- Failed to respond. XI.A (1-7) Failed to provide properly signed, undated and completed authorizations. . The authorizations that were provided are dated and are not completed per provider. The health insurance authorization is incorrectly filed out to the plaintiff and not the health insurance provider information.
3.	Keller, Theodore	20-cv-6918	Shrager & Sachs	Failed to File PFS
4.	Gunter, Alcus	20-cv-7952	Van Wey, Presby, & Williams, PLLC	Failed to File PFS

b. Second Listing Cases – Order to Show Cause Requested:

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these nine (9) cases were previously listed on the agenda for a prior CMC. Defendants provided a list including these cases and identified deficiencies to Plaintiffs' leadership counsel for distribution on November 17, 2020, met and conferred with Plaintiffs' counsel on November 19, 2020, and have been available for further meet and confers as needed. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why the case should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the November 24th Case Management Conference:

No.	Plaintiff	Civil Action No.	Law Firm	Core Deficiencies	Deficiency Notice Sent	Prior Agenda Listing
1.	Suits, James	2020 - CV- 6 547	Harrison Davis Steakley Morrison Jones, PC	See Deficiency notice. PFS is substantially incomplete, no authorizations provided. I.D.1 - Failed to attach records. - Records speak to a colonoscopy and polyp on 5/31/18, no definitive cancer diagnosis or treatment records provided. Please clarify diagnosis	9/5/ 20	October
2.	Pittman, Charlesto n	19 - CV- 1 5638	Law Offices of John D. Sileo LLC	See Deficiency notice. PFS is substantially incomplete. Authorizations are dated and not filled out to particular entities.	9/15/20	October
3.	Torghele, Dan	19-cv-21034	Shrager & Sachs	Section I is largely blank. XI.A.1 - Failed to provide properly signed, dated, and completed authorization.	3/26/20	October

				XI.A.6 - Failed to provide properly signed, dated, and completed authorization. XI.B.1 - Failed to respond. XI.B.6 - Failed to respond.		
4.	Terhune, Danny	1:20-cv-08211	Watts Guerra	Numerous deficiencies persist after the Amended PFS filing. See Deficiency Notice dated 9/18/20. Primary/core deficiencies in the Amended PFS are as follows: I.D.4 -7. Did not provide information on other types of cancer, if any. Did not provide information on cancer, staging, or remission. II.D.2 – No employment end date provided. III.E. – Did not answer questions about claimed emotional/mental injuries, if any. III.G. – Did not provide amounts of claimed medical expenses. IV.A. – Did not provide dates of treatment with Drs. Altneu and Lee, and did not indicate whether they are current providers. IV.D. – Did not provide dates of insurance coverage with Anthem Blue Cross. Please identify any other applicable insurance carriers.	9/18/20	October

				IV.G. – Did not provide information on treatments/providers for other conditions (depression/anxiety, diabetes, hyperlipidemia, HTN, obesity). VII.A.2. – Did not provide information on cancer diagnoses that are unrelated to Valsartan. For instance, did not identify type of cancer/primary oncologist for whatever condition required chemotherapy back in 2013. XI.A.1-7. – Some authorizations provided, but the following remain outstanding: social security disability; mental health, if applicable; IU Health Bloomington Hospital; and prescribing physicians - Dr. Ghosh, Dr. Anderson, Dr. Kaza.		

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5.	Welch, Durl	20-CV-07999	Watts Guerra	Deficient PFS. Deficiencies persist after the Second Amended PFS filing. See Deficiency Notice dated 9/18/20. Deficient PFS. Deficiencies persist after the Second Amended PFS filing. See Deficiency Notice dated 9/18/20. I.D.1 –Provided medical records from Oklahoma Cancer Center and St. John's Hospital, but failed to provide medical records from Kevin Keller, M.D., demonstrating cancer diagnosis or other alleged injury. No records provided from initial cancer diagnosis in February, 2016. III.G.a - c - Failed to provide information regarding medical expenses and instead states "will supplement." XI.B.2 - Pharmacy records and records from Oklahoma Cancer Center and St. John's Hospital were provided, but no additional medical records from Kevin Keller, M.D. were produced	9/18/20	October
6.	Belcuore, Patrick	20-CV-07787	Watts Guerra	Yes. See Deficiency Notice of 9/14/20. All deficiencies remain from 9/14/20 Deficiency Notice except for new sufficient responses to XIB.4 – XI.B.23. All core deficiencies present.	9/14/20	October

7.	White, Linda	20-cv-03885	Watts Guerra, LLP	I.D.5 - Failed to respond. Highest stage diagnosed for 4/19 diagnosis. III.A - Failed to respond. Date of first hypertension diagnosis. III.G - Failed to respond. Medical expenses. V.D - Failed to respond. Date tobacco use started and amount used. V.G - Failed to respond Date of onset, treatment received and outcome for hypertension.	7/6/2020	October
8.	Noble, Maria	20-cv-08100	Watts Guerra LLP	I.D - Failed to respond. Section 1.D (alleged injury). III.A.1.a - Failed to respond. When were you first diagnosed with hypertension? Plaintiff offers no response. III.B.6 - Failed to provide complete information. Please identify the advertisement or commercial, and state the nature and content of each that	9/18/2020	October

				plaintiff claims to have seen in 2018. III.G.b - Failed to respond. Date of expenses. III.G.c - Failed to respond. Expenses. IV.B.4 - Failed to respond. Reason for treatment at Javon Bea Hospital. IV.E - Failed to respond. Section IV.E (witnesses). V.D. - Failed to respond. Information related tobacco use. V.E. - Failed to respond. Type of alcohol consumed. V.G. - Failed to respond. Onset dates for all conditions listed, including hypertension. VI.A. - Failed to respond. Dates for all medications listed. VIII. - Failed to respond. Section VIII (family medical history).		
9.	Carnley, Ralph	20-cv-07946	Wattas Guerra, LLP	I.C.2 - Failed to attach records. Documents showing product use.	9/18/2020	October

				I.C.3 - Failed to respond. Dosage of valsartan plaintiff clams to have taken. I.C.10 - Failed to provide complete information. Start date of valsartan use. I.D.5 - Failed to respond. Highest stage diagnosed for liver and pancreas cancers. I.D.6 - Failed to respond. Metastasis of Cancer to other Organs? I.D.7 - Failed to respond. Remission Date (if applicable). I.D.8 - Failed to respond. Description of treatment for cancers. III.G.c - Failed to respond. Medical expenses. XI.A.1 - Failed to provide properly signed, undated, and completed authorization. XI.A.6 - Failed to provide properly signed, undated, and completed authorization. XI.B.1, 2, 4, 10 - Failed to attach documents that plaintiff claims to have attached.		

				XII - Failed to provide signed and dated, declaration.		

c. First Listing Cases – Remaining Core Deficiencies

The following Plaintiff Fact Sheet contains core deficiencies which remain unresolved. Defendants provided a list including these cases and identified deficiencies to Plaintiffs on November 17, 2020 and met and conferred with Plaintiffs' counsel on November 19, 2020 and have been available for further meet and confers as needed. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

No.	Plaintiff	Civil Action No.	Law Firm	Core Deficiencies	Deficiency Notice Sent
1.	Ramirez, Richard	20-cv-05595	Watts Guerra, LLP	No authorizations filed No records filed	7/27/20
2.	McClennon, Jacqueline	20-cv-11079	Watts Guerra	See deficiency notice – no auths produced	11/10/20
3.	Hawkins, Fledia	20-cv-8681	Hollis Law Firm, P.A.	I.C.3-I.C.11 – Plaintiff only identified one Valsartan product in the Amended PFS for the time period of 6/17/2015-9/25/2017. However, the produced pharmacy records contain two Valsartan products: one product for the time period of 8/6/2014-5/10/2015 and a second product for the time period of 6/17/2015-9/25/2017. III.C.5 - Plaintiff stated that she took blood pressure medication for a minimum of 6 months at the time she was diagnosed with the alleged injury(ies) she claims resulted from Valsartan use. However, Plaintiff did not specify which blood pressure medication(s) she took during the referenced time period.	10/19/20

				XI.B.2 - Plaintiff stated in the PFS that her cancer diagnosis date was 10/24/2017. There were medical records produced from 10/24/2017, however the produced medical records from 10/24/2017 reference a biopsy report from earlier on the same date that diagnosed Plaintiff's cancer. The referenced biopsy report that diagnosed Plaintiff's cancer was not produced.	
4.	Hardcastle, Evelyn	20-cv-8659	Hollis Law Firm, P.A.	I.C.2 – Plaintiff stated that there is a Valsartan container of packaging in her possession in section III.B.5 of the PFS. However, no photographs of the referenced container or packaging were produced. I.C.4 & I.C.7 – The produced pharmacy records contain two Valsartan products that were used by Plaintiff and show the Valsartan use time periods as 8/27/2014-5/29/2015 and 8/31/2015-10/16/2017. However, the PFS only includes one Valsartan product and identifies the Valsartan use time period as 8/31/2015-1/14/2018. I.D.8 - Plaintiff states the treatment she received in relation to her cancer diagnosis as "diet and lifestyle changes." Please clarify whether Plaintiff received any medical treatment or surgery following her cancer diagnosis on 1/15/2016. III.G.c - Plaintiff failed to provide any substantive response regarding the monetary amount for the claimed medical expense.	10/19/20

				XI.A.1 - No health care authorizations produced for: Walgreens; Kroger; or Cleburne Memorial Hospital. Please produce properly executed and undated health care authorizations for said pharmacies and treating facility. XI.B.3 - Plaintiff states that her radiology films have been produced, however no imaging has been produced by the Plaintiff. XI.B.18 - Plaintiff failed to provide billing records in relation to the claimed medical expenses. XII – Plaintiff did not produce a declaration with the PFS.	
5.	Bird, Susan	20-cv-7844	Watts Guerra, LLP	I.D.1 Failed to attach records. Records showing injury. I.D.2 Failed to provide original date of cancer diagnosis, type of cancer, other cancers, highest stage diagnosed, answer regarding metastasis, or treatment procided. III.G.a Failed to respond. Medical expenses. XI.A.6 Failed to provide witnessed and undated authorization.	9/15/2020
6.	Smoot, Kelly	20-cv-8560	Watts Guerra, LLP	I.C.10 Failed to respond. Start and end date for valsartan prescribed by Dr. Wittles. I.D.1 Failed to attach records.	9/25/2020

				Records showing injury. II.D.4.c Failed to respond. Whether and for what period diet includes red and/or processed meats. II.D.4.d Failed to respond. Whether and for what period diet includes smoked foods, salted meat and fish, and/or pickled vegetables. III.F.2.a Failed to respond. Annual gross income for years 2011-2015 (plaintiff is claiming lost wages). III.F.3.a Failed to respond. Annual gross income for years 2017 to 2019 (plaintiff is claiming lost wages). III.F.4.a Failed to respond – total income lost (plaintiff is claiming lost wages). III.G.c Failed to respond. Date and expenses for Witham Health Services and Dr. Wittles. XI.A.2 Failed to provide properly signed, undated, and completed authorization (tax forms).	
7.	Paul, Rebecca	20-cv-08362	Watts Guerra, LLP	I.B Failed to respond. Social security number for plaintiff and spouse. II.C-K Failed to respond. Sections II.C to K.	9/25/2020

				III.A.1.a, b Failed to respond (hypertension history). III.B.2 Failed to respond – Valsartan samples. III.B.6, 7 Failed to respond Sections B.6 and 7 III.C Failed to respond. Sections III.C to F. III.G Failed to respond. Section III.G -- Medical expenses. III.H Failed to respond. Section III.H IV.B.1 Failed to respond. Information for hospital where hip surgery was performed. IV.E Failed to respond. Section IV.E -- Other witnesses. V.G.2 Failed to respond. Name, address and phone number of treating health care provider for all conditions listed. V.G.3 Failed to respond. Approximate date of onset for all conditions listed. V.G.4 Failed to respond.	

				Treatment received and outcome for all conditions listed. VI.A.2 Failed to respond. Healthcare provider(s) that prescribed all of the medication listed. VI.A.3 Failed to respond. Approximate dates/years when all medications listed were taken. VI.A.6 Failed to respond. Name and address of pharmacy for all medications listed. VI.B.2 Failed to respond Healthcare provider(s) that prescribed/recommended all medications listed. VI.B.3 Failed to respond. Approximate dates/years all medications were taken. VI.B.5 Failed to respond. Reason for use for all medications listed. VI.B.6 Failed to respond. Pharmacy/Store where all medications were purchased. VIII Failed to respond (family cancer history). Family member name.	

				Age at diagnosis. Date of diagnosis. Treatment and Outcome XI.A No authorizations submitted. XI.B.14 Failed to provide records requested. XII Failed to provide signed and dated, declaration.	
8.	Troyce, Houchin	20-cv-08269	Pendley, Baudin & Coffin, L.L.P.	Failed to file amended PFS *See Deficiency Notice*	10/27/2020
9.	Cambron, John	20-cv-09345	Watts Guerra, LLP	Failed to file amended PFS *See Deficiency Notice*	10/13/2020
10.	Aikens, Thomas	20-cv-5187	Law Offices of Henry Schwartz	Failed to file amended PFS *See Deficiency Notice*	10/06/2020
11.	Lomax, Sharon	20-cv-05176	Law Offices of Henry Schwartz	Failed to file amended PFS *See Deficiency Notice*	10/06/2020
12.	Napolitano, John	20-cv-05174	Law Offices of Henry Schwartz	Failed to file amended PFS *See Deficiency Notice*	10/06/2020
13.	Hebert, Betty	19 - CV- 14647	Damon J. Baldone	No authorizations or records uploaded.	7/27/2020

d. First Listing Cases – Failure to File PFS:

The following plaintiffs have failed to file a Plaintiff Fact Sheet and are beyond the deadline to file. Defendants provided a list including these cases to Plaintiffs on November 17, 2020 and met and conferred with Plaintiffs' counsel on November 19, 2020 and have been available for further meet and confers as needed. This is the first time these cases have been listed

on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	PFS Due
1.	Lehr, William	20-cv-07454	Brown, LLC	No PFS filed	9/13 + 30 day extension
2.	Locke, Donna	20-cv-08770	Levin Papantonio	No PFS filed	9/18/2020
3.	Schiano, John	20-cv-08677	Hollis Law Firm	No PFS filed	10/2/2020
4.	Newcombe, Sonja	20-cv-10274	Levin Papantonio	No PFS filed	10/10/2020
5.	Williams, Naomi	20-cv-08772	Levin Papantonio	No PFS filed	9/18/2020
6.	Ware, Johnny	20-cv-10365	Levin Papantonio	No PFS filed	10/20/2020
7.	Gibson, James	20-cv-2875	Douglas & London	No PFS filed	10/31/2020
8.	Hightower, Lyrik	20-cv-12482	Oliver Law Group	No PFS filed	11/8/2020
9.	Walsh, Fannie	20-cv-11836	Stark & Stark	No PFS filed	11/1/2020
10.	Thomas, Euric	20-cv-12440	Hollis Law Firm	No PFS filed	11/7/2020

5. Teva's Proportionality Motion

On November 19, 2020, the parties submitted simultaneous supplemental briefing on this issue as requested by the Court. The issue is fully briefed and Teva will be prepared to present argument on any outstanding issues at the November 24, 2020 Case Management Conference.

6. Wholesaler discovery issues.

Wholesalers received a letter on November 18, 2020 setting out alleged deficiencies in Wholesalers' responses to Plaintiffs' Second Amended Set of Requests for Production of Documents and requesting a meet and confer by November 20, 2020. Due to the issues raised in Plaintiffs' letter, counsel for all three Wholesaler Defendants need to participate in order to have a meaningful discussion. As such, Wholesalers replied to Plaintiffs on November 20, 2020,

offering several dates on which all parties can meet and confer during the week of November 30, 2020, after the Thanksgiving holiday. A copy of that correspondence is attached as Exhibit L hereto. To date, there has been no reply.

It is Wholesalers' position that any attempts by Plaintiffs to obtain rulings at the status conference on alleged discovery deficiencies that have not been the subject of a meet and confer is improper and premature. Wholesalers' counsel will be prepared to address any remaining alleged deficiencies, to the extent necessary, after the parties have had an opportunity to meet and confer.

7. ZHP production issues

During a meet and confer on November 6 regarding ZHP's document production, Plaintiffs' counsel posed an unrelated question regarding whether ZHP ever manufactured valsartan API and finished dose products outside of the two facilities that ZHP has previously stated are the sites where it manufactures valsartan products – Chuannan and Xunqiao. ZHP's counsel responded that they did not believe any valsartan products were manufactured outside of these two sites, and Plaintiffs' counsel stated that she would follow up by letter with references to documents in Defendants' productions. By follow-up email of November 11, *see* Exhibit M, Plaintiffs' counsel accused ZHP of failing to disclose valsartan manufacturing sites, citing several production documents. However, upon review, the documents cited by Plaintiffs did not state that ZHP manufactured valsartan products at sites other than Xunqiao and Chuannan, and, after conferring with its client, ZHP's counsel confirmed that ZHP has only manufactured valsartan API and finished dose products at Chuannan and Xunqiao. In subsequent email exchanges, Plaintiffs continued to make unfounded accusations against ZHP, and attempted to go beyond the scope of this Court's discovery orders by demanding expansive information regarding manufacturing sites for what they broadly described as "starting materials and/or intermediates" manufactured by ZHP or any of its subsidiaries, despite that fact the Court's Macro Discovery Order (ECF Doc. No. 303) limits discovery to facilities that have manufactured valsartan API or finished dose products for sale in the United States. *See also* Tr. of Apr. 10, 2019 Conference at 31:14-17 (Noting that that one of the purposes of Defendants' production of "core discovery" was to "guide [Plaintiffs'] discovery in this case so [Plaintiffs] don't go down a rabbit hole."). Notably, the Court's order is consistent with the FDA's investigation into the nitrosamines impurities, which has been limited to the Chuannan and Xunqiao sites.

As ZHP is a public company, it has agreed to produce a list of all of its subsidiaries to Plaintiffs, despite the fact that most of its subsidiaries are completely unrelated to the Plaintiffs' claims. However, ZHP objects to producing any documents or information that goes beyond the Court's discovery orders, and requests that the Court put an end to Plaintiffs' burdensome and harassing requests so that the parties can focus on completing discovery that is within the scope of this Court's orders.

8. State Litigation

Federal Cases

Case	Court	Assigned Judge	Status
Harris v. Aurobindo Pharma USA, et al., 3:20-cv-00609	M.D. Ala.	Hon. Emily C. Marks	Plaintiff's Motion to Vacate Conditional Transfer Order ("CTO") pending before the JPML
Hernandez v. Aurobindo Pharma USA, et al., 8:20-cv-02409[10]	M.D. Fla.	Hon. Charlene Edwards Honeywell; Hon. Julie S. Sneed (Magistrate Judge)	Removed from state court on 10/15/20

State Cases

Case	Court	Assigned Judge	Status
Brown v. Camber Pharmaceuticals, et al., No. 35-cv-2020-900037	Circuit Court of Greene County, Alabama	Hon. Eddie Hardaway, Jr.	Motion to dismiss filed and pending
Smith v. Torrent, et al., No. 9-cv-2020-900036	Circuit Court of Bullock County, Alabama	Hon. Burt Smithhart	Answer filed
Hall v. Torrent, et al., No. 66-cv-2020-900047	Circuit Court of Wilcox County, Alabama	Hon. Collins Pettaway, Jr.	Motion to dismiss filed and pending
Wilson v. Camber, et al., 27-cv-2020-900186	Circuit Court of Dallas County, Alabama	Hon Marvin W. Wiggins	Motion to dismiss filed and pending

[1] On October 22, 2020, the JPML decided that this case was not appropriate for inclusion in the MDL. Counsel are considering next steps for including this case in the MDL.

Shanov v. Walgreens Boots, Inc., 2020CH01884	Circuit Court of Cook County, Illinois	Hon. Anna Helen Demacopoulos	Motion to dismiss (or, in the alternative, to stay, or to join a defendant) filed and pending
Rafuls v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al., MID-L-4629-20 (N.J. Super.)[11]	New Jersey Sup. Ct. Middlesex County	Hon. Patrick Bradshaw	No affidavit of service filed as of 10/22/20
Mooradian v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al., MID-L-4603-20 (N.J. Super.)	New Jersey Sup. Ct. Middlesex County	Hon. Christoph Rafano	No affidavit of service filed as of 10/22/20
Franco v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al., MID-L-4602-20 (N.J. Super.)	New Jersey Sup. Ct. Middlesex County	Hon. Christoph Rafano	No affidavit of service filed as of 10/22/20
Cardy v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al., MID-L-4599-20 (N.J. Super.)	New Jersey Sup. Ct. Middlesex County	Hon. Christoph Rafano	No affidavit of service filed as of 10/22
Debose v. Zhejiang Huahai Pharmaceutical Co., Ltd. et al., MID-L-4601-20 (N.J. Super.)	New Jersey Sup. Ct. Middlesex County	Hon. Christoph Rafano	No affidavit of service filed as of 10/22

[11] Similar to the New Jersey Superior Court cases listed below, Plaintiffs have agreed to enter stipulated orders to hold *Rafuls*, *Mooradian*, *Franco*, *Cardy*, and *Debose* in abeyance. Plaintiffs have represented that once the number of cases reaches the necessary threshold for a Multicounty Litigation ("MCL") application, such an application will be made. If an MCL is established, Defendants expect a formal coordination order will be granted. If an MCL is not granted, Defendants expect that they will work to execute coordination orders in each action.

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Federal Cases—Stayed

Case	Court	Assigned Judge	Status
Thorn v. Mylan Pharmaceuticals, et al., Case No. 2:20-cv-00442	S.D. Ala.	Hon. Kristi K. DuBose; Hon. William E. Cassidy (Magistrate Judge)	Stayed (pending decision by JPML on transfer); Plaintiff's Motion to Vacate CTO pending before JPML
Smiley v. Aurobindo Pharma USA, Inc., et al., 2:20-cv-00416	S.D. Ala.	Hon. Kristi K. Dubose; Hon. P. Bradley Murray (Magistrate Judge)	Stayed (pending decision by JPML on transfer); Plaintiff's Motion to Vacate CTO pending before JPML
Pace v. Solco Healthcare U.S., LLC, 3:20-cv-00595	M.D. Ala.	Hon. Stephen Michael Doyle	Stayed (pending decision by JPML on transfer); Plaintiff's Motion to Vacate CTO pending before JPML

State Cases—Held in Abeyance

Case	Court	Assigned Judge	Status
Pedrick v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al., MID-L-4616-20 (N.J. Super.)	New Jersey Sup. Ct. Middlesex County	Hon. Bruce Kaplan	Held in Abeyance
Dessoye v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al., MID-L-4614-20 (N.J. Super.)	New Jersey Sup. Ct. Middlesex County	Hon. Thomas D. McCloskey	Held in Abeyance

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Byrum v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al., MID-L-4590-20 (N.J. Super.)	New Jersey Sup. Ct. Middlesex County	Hon. Thomas D. McCloskey	Held in Abeyance
Wiltshire v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al., MID-L-4593-20 (N.J. Super.)	New Jersey Sup. Ct. Middlesex County	Hon. Thomas D. McCloskey	Held in Abeyance
Lippl v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al., MID-L-4591-20 (N.J. Super.)	New Jersey Sup. Ct. Middlesex County	Hon. Bruce Kaplan	Held in Abeyance
Orlowsky v. Prinston Pharmaceutical Inc., et al., No. MID-L-0002554-19 (N.J. Super.)	New Jersey Sup. Ct. Middlesex County	Hon. J.R. Corman	Held in Abeyance
Robertson v. Prinston Pharmaceutical Inc., et al., No. MID-L-004228-19 (N.J. Super.)	New Jersey Sup. Ct. Middlesex County	Hon. Patrick Bradshaw	Held in Abeyance
Garnes v. Zhejiang Huahai Pharmaceutical Co., Ltd., No. MID-L-005191-19 (N.J. Super.)	New Jersey Sup. Ct. Middlesex County	Hon. Thomas D. McCloskey	Held in Abeyance

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Respectfully submitted,

/s/ Lori G. Cohen

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